EU DECLARATION OF CONFORMITY

Document number: ALDP275101220331

Following the provisions of the medical device's regulation 2017/745(EU MDR).

We:

Legal Manufacturer	EU Authorized Representative
CV. Anggrek-Liar Jalan Jomblang Barat 666 RT 09 RW 03 Kelurahan Candi, Kecamatan Candisari Semarang 50257 Central Java REPUBLIC OF INDONESIA	Kaio-Dia Europe Sasu 12, rue Bertrand 31480 Lagraulet Saint Nicolas, France
Single Registration Number (SRN) ID-MF-000037819	Single Registration Number (SRN) FR-AR-000037267
Manufacturing Sites	
Anggrek-Liar / Kaio-Care Jalan Tumpang IV No. 38 Kelurahan Bendan Ngisor Kecamatan Gajahmungkur Semarang 50233 Central Java REPUBLIC OF INDONESIA	MAF Holding BV Laan van Leeuwesteyn 62 2271 HL Voorburg, Nederland Single Registration Number (SRN) NL-AR-000044388

Declare under our sole responsibility for the universal device fixation support:

Kaio-Dia® Dia-Pouch©
Non-Invasive Pouch

Basic UDI-DI:
8994228UP-DP19M

Identification number:
See Appendix 1

SIGNATURE:  Date: 18 December 2024

Date of Issue :
Place of Issue : Semarang, Central Java, Indonesia
Name : Anik Susilawatiningsih
Function : Regulatory Affairs Manager

This Declaration of Conformity relating to Technical Documentation DOC275DP41292 supersedes the previous Declaration signed 01-December-2021.

Intended Purpose:

Kaio-Dia® Dia-Pouch©, a pouch are independently developed as universal after market accessories used to provide additional fixation support for a wide variety of automated insulin and medication on body delivery systems.

(see attachment **Appendix 1 – List of Supported Product version #2**)

Dia-Pouch© are available in various design and colors are non-sterile and may be reused (intended for single patient use only).

The devices are not designed or sold for use other than indicated.

EMDN code and description:
Z12040180 - GENERAL MEDICINE INSTRUMENTS FOR DIAGNOSIS AND MONITORING - HARDWARE

Class: I

Classification rule (Annex VIII): 1

to which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 (EU MDR).

This conformity is based on the following elements:

- Technical Documentation reference: DOC275DP41292, of the product to which this declaration relates.

As a Class I medical device, this product is self-certified in accordance with Regulation (EU) 2017/745. The conformity assessment has been carried out under the sole responsibility of the manufacturer, without the involvement of a Notified Body.

The undersigned, acting on behalf of CV. Anggrek-Liar, assumes full responsibility for ensuring that the product complies with all applicable European laws and regulations.

SIGNATURE: 

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Appendix 1 – List of Supported Product

Date: 08-12-2024 Version number #2

Producer	Product Name	
Medtronic	Minimed™ 630g	
Medtronic	Minimed™ 770g	
Medtronic	Minimed™ 780g	
Tandem	T:slim X2™	
Ypsomed	Mylife™ YpsoPump®	
SOOIL	Diabecare DANA-i	
SOOIL	Dana Diabecare RS	
SOOIL	Dana Diabecare R	
SOOIL	Dana Diabecare IIS	

End of Document

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